USP Class VI Biocompatibility Certificate

For Accura ClearVue Material

Certificate Number: FL-ACCURA-CLEARVUE-BC-202611

USP Class VI Biocompatibility Certification

This is to certify that the material **Accura ClearVue** has been evaluated and found to comply with USP <87> Biological Reactivity Tests, In Vitro and USP <88> Biological Reactivity Tests, In Vivo plastic Class VI requirements when processed according to the specified cleaning protocol.

Compliance Standards

- USP <87> - Biological Reactivity Tests, In Vitro
- USP <88> - Biological Reactivity Tests, In Vivo
- ISO 10993-1 - Biological evaluation of medical devices
- FDA 21 CFR 177.1500 - Nylon resins
- 3D Systems Customer Information Bulletin CIB00262

Test Methods & Validation

Material validation performed according to 3D Systems Customer Information Bulletin CIB00262 "Accura ClearVue Cleaning Procedure for USP Class VI Compliance". Testing includes systematic extraction, culture medium mammalian cell culture, agar diffusion, and intracutaneous reactivity assessments.

Intended Use

This certification applies to medical applications with limited contact duration and non-implantable devices. Suitable applications include:

- Medical Models: Anatomical and device models for medical visualization and educational purposes

Important Limitations and Warnings

- This certification is valid only when the specified 5-cycle cleaning protocol is followed exactly
- Not suitable for long-term implantation or permanent body contact applications
- Material traceability documentation must be maintained for all biocompatible parts
- Re-certification required for any process modifications or extended storage periods

Required 5-Cycle Cleaning Protocol

The following cleaning procedure MUST be followed to maintain USP Class VI compliance:

Step 1: Initial Preparation

• Remove all supports and perform initial cleaning • Use clean nitrile gloves (change between cycles) • Prepare 5 separate containers with 99%+ isopropanol

Step 2: Initial Soak (20 minutes)

• Submerge parts completely in first container • Gentle agitation every 5 minutes • Use soft brush for surface cleaning (new brush for each cycle)

Step 3: Four Additional Cycles (5 minutes each)

• Transfer to fresh isopropanol container • Gentle agitation and brushing • Change gloves between each transfer

Step 4: Drying (6-10 hours)

• Air dry in contamination-free environment • Protect from dust and environmental contaminants

Step 5: Post-Curing

• PostCure 1050: 1 hour per side at recommended temperature • Allow cooling before handling

Step 6: Final Inspection & Packaging

• Visual inspection for contamination • Clean packaging in sterile environment • Document cleaning protocol completion

Quality Assurance Manager

Date: _____

Technical Director

Date: _____

Certificate valid until: November 10, 2028

This document is computer-generated and valid without signature.